DEPARTMENT OF HEALTH AND MENTAL HYGIENE
MARYLAND AIDS ADMINISTRATION
and
LABORATORIES ADMINISTRATION

PROTOCOLS
for
HIV Counseling and Testing

Using the OraQuick ADVANCE® testing system

Laboratory Quality Assurance Manual

Modified for Maryland sites using OraQuick ADVANCE®

This document is intended to help organizations create a QA Manual

November 2004

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Worksheets: (blank copies, current procedures only)

- Individual Competency Record
- Site Competency Summary
- Monthly Test Volume Summary
- Corrective Action forms
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Introduction

This manual is intended as a guide to serve the needs of clinical sites performing the OraQuick ADVANCE® HIV procedure to create a working document. It can be "customized" for each site because no generic document can serve all sites acceptably. The Laboratory Director should assist the local Site Coordinator in completing this document as necessary. It will be the Site Coordinator's responsibility to post the document in an accessible location as part of a Regional Laboratory System to insure that all testing personnel have reviewed the document. If you have older copies of a "Laboratory Quality Assurance Manual" you can update them with the material in this document. If your facility does not have a Quality Assurance Manual, this document, once customized, can serve as the required manual.

The basic document is available in both hard copy and on a reference diskette as a MS-Word document. It is intended that each site use the basic document on diskette and add their own site specific information to the document.

At a minimum:

1. The title page should contain the name of the site and site address(es).
2. Additions should be made to cover specific situations at your local health facility.
3. Wherever the term *"Your Local Health Department*" appears, it should be replaced with the actual name of your health facility name.
4. Wherever a specific person is supposed to be listed, e.g. "The person in charge of maintaining the QC records is: ___." you must replace the blank (___) with the appropriate persons name.
5. Wherever a specific location is indicated "e.g.: the QC records will be located in ____" you must replace the blank with the location appropriate for your facility.
6. Wherever there are instructions for you to INSERT your example document or form in the Appendix, you must include a copy of the document or form that is actually used at Your Local Health Department.

Laboratory Manuals

There should be three "laboratory manuals" They may be combined into one volume or divided into three volumes as the needs of the laboratory dictate. In any case, all of this material must be readily available to the personnel who perform the test procedures.

A Procedure Manual will contain specific information which address:

1. Guidelines
2. Policy
3. Specimen collection
4. Testing procedures.
5. It may contain a section on communications and various directives sent to the facility from time to time.

A Safety Manual will contain specific instructions and guidelines which address:

1. Laboratory Safety Guidelines and other pertinent safety documents for *Your Local Health Department.*
2. Blood Borne Pathogen Standard
3. Biohazards and Waste Disposal Plan*
4. MSDS sheets, and Right to Know information
5. Chemical Hygiene*

*A site using the OraQuick ADVANCE® test only should not need these items.

The Laboratory Quality Assurance Manual (this document)

I. Purpose, Mission Statement, Goals, and Objectives

Purpose: The purpose and intent of this Quality Assurance Manual is to formalize and standardize the quality assurance practices at *Your Local Health Department* and throughout the Regional Laboratory System.

Mission Statement: The mission of this laboratory service is to provide timely analytical data which is accurate, reliable, and relevant to public health, clinical or epidemiological program needs. The Quality Assurance Manual will provide a framework for personnel at *Your Local Health Department* to implement a clinical testing program of high quality and value to the public.

Vision Statement: The voluntary affiliation of *Your Local Health Department* along with other public health professionals in the Regional Laboratory System will strengthen public health programs throughout Maryland. All participants or affiliates of the Regional Laboratory System from laboratory directors to testing personnel and their supervisors and administrators are committed to strive for continuous improvement in testing quality and service delivery.

Goals: The goals of the *Your Local Health Department*, through participation in the Regional Laboratory System are to achieve, to the extent possible, excellence in clinical testing and performance. This will be achieved through continuously monitoring and evaluating quality of testing performance, and identifying interventions which will improve testing quality and be responsive to the needs of the community and public health programs. The Regional Laboratory System will provide a mechanism for local health departments to meet the quality assurance program requirements of federal laboratory testing standards, the Clinical Laboratory Improvement Amendments of 1988 (CLIA'88).

Objectives: To pursue the above stated goals, the *Your Local Health Department* will address the following objectives:

1. To assure that patient test results are accurate and complete.
2. To encourage uniformity in testing procedures and quality assurance practices performed in all participating testing sites.
3. To rapidly identify and correct problems encountered while following written procedures.
4. To ensure that records are maintained that permit the evaluation of the quality and reliability of the data produced.
5. To provide both the professional and non-professional staff with the cost-efficient procedures, reagents and equipment needed to confidently perform testing and implement this quality assurance program.
6. To assure sample identity, integrity and quality.
7. To identify needs and provide training and other resources required to maintain and improve the skills of the staff.

Responsibility: It is the responsibility of each person involved in laboratory testing to implement or facilitate implementation of quality assurance programs according to his/her assigned duties. Although quality assurance activities may be delegated, it is essential that each person in the process is committed to continuously consider the laboratory system as a whole and strive to improve its function.

II. General Overview

With the advent of CLIA'88 regulations and their application to all facilities which perform any clinical testing, the issue of routine Quality Control (QC) has caused some confusion. This section is an overview of the subject and a general outline of the procedure(s) that the Regional Laboratory System provides. CLIA'88 recognizes, at present, three categories of testing; waived tests, moderately complex and complex testing. The Regional Laboratory System falls in the moderately complex category, even though many of its tests would are classified in the waived category. The OraQuick ADVANCE® test is classified in the waived category. While not strictly required by CLIA'88 for waived category tests, the QC protocol we apply is the same for all tests regardless of the category in which they are placed. This is based on standard laboratory procedure for good laboratory practice. After all, if the test is worth doing at all, then it is worth insuring that the result is meaningful!

There are two broad categories of tests, quantitative and qualitative. Quantitative tests attempt to determine "how much" or "how little". Cholesterol values are a typical quantitative test. Qualitative tests attempt to determine whether or not a specific condition exists ("yes" or "no"). The OraQuick ADVANCE® is a typical qualitative test. Each type of procedure has its own QC requirement. For quantitative tests, the QC procedure should challenge the test with at least low and high value controls over the range of the test. Choice of actual control materials usually depends upon what break-points are important. For quantitative tests, there is usually a normal range for which determinations below normal or above normal are clinically significant. Thus the control materials would be chosen to fall at the break-point between low and normal on one side and between normal and high on the other side. Control materials for qualitative tests, like OraQuick ADVANCE®, utilize material which will yield a positive or a negative result. Some test kits, including OraQuick ADVANCE®, have "internal QC indicators". While internal controls are good, they do not take the place of challenging the test with known positive and negative specimens from a standardized source. In many cases, standardized QC materials can be obtained from the kit manufacturer.

Implied in any QC program is that persons using the test have been instructed so that they can perform the procedure according to written instructions and their competency is documented. A written procedure will be placed in a lab manual available at the testing site, and the procedure will adhere to any conditions specified by the reagent or test manufacturer. The test materials must be stored according to the conditions specified in the procedure. YOU MAY NOT use expired materials for patient testing under any circumstances. No test should ever be performed on clinical specimens if the QC test(s)

has not been performed or has failed. All of these conditions must be met before the test ever used for clinical testing.

QC Testing Volume: So how much testing is enough? It depends on several factors which will be specific to the test in question. However, there are some general guidelines.

1. It is important to test reagents, or kits, once before they are placed into service; we don't want to learn that a new lot of OraQuick ADVANCE® tests are not working on the day all of the old reagents are exhausted or expired.
2. If a test is considered in the waived category by CLIA'88, then at least one control is required. It will be our standard practice to test three controls, an HIV-1 positive (abnormal), an HIV-2 positive (abnormal), and a negative (normal) at some interval specific for each test.
3. Since the OraQuick ADVANCE® test utilizes no testing equipment, calibration verification is not required.
4. The initial QC tests must be done when a new kit is opened, before any patient specimens are reported. QC should also be run each shift that the test is performed, concurrently with the first patient sample.

Recording: QC information will always be placed in its own log sheet. Record the lot number and expiration date of the test material on the patient log sheet too; that way it is easy to cross check QC test with the material that was used for patient testing. Other QC data should not be recorded on the patient log sheet.

Write it down! One of the most common mistakes made in any QC program is the failure to document results and any corrective action that was taken.

1. The QC log sheet will usually have the following kinds of information:
   a. Name of the test at the top of the sheet
   b. Name of Manufacturer
   c. Lot number, expiration, and expected result of controls
   d. Date of individual test
   e. Lot number of the kit or reagent system
   f. Date of expiration of the kit or reagent system observed results (e.g. reactive, non-reactive, equivocal) or quantitative values. Including if appropriate;
      1) Closed vial expiration date (the date on the vial)
      2) Open vial expiration date (when an opened vial will expire, e.g. in 21 days)
   g. Pass or Fail column
   h. Initials column for person performing the QC test.
   i. Corrective action section to note what was done in case QC tests yielded unexpected results (i.e. QC failed).
   j. Sign-off for Site Coordinator at the bottom of the sheet (name and date)
   k. Sign-off for Laboratory Director at the bottom of the sheet (name and date)
2. It is common practice for an inspector to ask for clinic records, identify dates when the test procedure was performed, and then ask to see the QC records for that specific date and proof that test results were placed in the client's chart.

Errors: If you happen to make an error by entering incorrect information or placing information in the wrong blank, draw a single line through the mistake(s) and initial the line in the margin. Don't ever try to scribble over errors or use white out to cover them up - inspectors and lawyers assume that you are trying to hide something.

Well documented QC testing and appropriate corrective action are the best indication that you and your staff have approached clinical testing in a professional manner using good laboratory practices.

QC Testing Interval: While subject to change depending upon experience and the discretion of the Technical Coordinator and Laboratory Director, the following intervals will be considered standard for Quality Control;

Quality Control Intervals

TEST	Open New Lot No.	Each Shift	Each Week	Each Month	When Moved
OraQuick ADVANCE® HIV	Yes	Yes	N/A	N/A	Sometimes*

*If test system is moved to a new location where temperature or other environmental factors varies significantly from the initial area where QC was performed, QC should be repeated. Check the manufacturer instructions.

Review of Quality Control Records: The Site Coordinator should review and sign all QC records each month. Flag records that have not been signed by the Laboratory Director so that (s)he can sign them on the next visit. Alternatively if there is a quality control problem or there is a significant interval between laboratory visits by the Laboratory Director, the form(s) should be mailed in when completed for review and signature. The process will be as follows:

2. Site Coordinator reviews sheet at the end of the month. Initial any corrective action if not already reviewed.
3. Site Coordinator signs and dates sheet.
4. Site Coordinator records date to mail in the "sent to Director" section, and post a Xerox copy in the QC file.
5. Site Coordinator mails the original copy to the Director for review and signature.
6. Director reviews, signs QC log sheets and returns them to the Site Coordinator
7. Site Coordinator dates returned section of QC log sheet and replaces Xerox copy with the original in the Log Book.

The review process should begin during the first week of each month for the previous month. QC records for the previous two months should be maintained at the testing site in a sturdy binder. Older records are maintained by the Site Coordinator in a central

location for two years. The Site Coordinator should keep the Xerox copies on file until they have the original log sheets are in their files.

III. Personnel

Personnel Qualifications and Responsibilities: The CLIA'88 legislation requires that the following positions are defined and have specific personnel requirements depending upon the complexity level (waived, moderate or high). The Regional Laboratory System contains both moderate and high complexity testing facilities. All personnel associated with laboratory activities must meet or exceed CLIA'88 personnel requirements.

Table 2

CLIA defined positions and requirements

for each level of testing complexity

Position Standards	**Waived (low complexity)**	**Moderate Complexity & PPMP**	**High Complexity**
Medical Officer	Not required by CLIA, defined as a matter of operational efficiency. This person may be listed and act as the "Clinical Consultant"		
Laboratory Director	no standard	required	required
Technical Consultant or Supervisor	no standard	required	required
Clinical Consultant	no standard	required	required
General Supervisor	no standard	no standard	required
Site Coordinator	Not required by CLIA, defined as a matter of operational efficiency. This person may be listed and act as the "General Supervisor"		
Testing Personnel	no standard	required	required

The following references are taken from the Federal Register 55(50): March 14, 1990.

Medical Director: (addressed under Laboratory Director) The Health Officer may, if qualified, perform the duties of Laboratory Director. In most cases, the Health Officer (if qualified) or Medical Director serves as the Clinical Consultant.

1. Physician (MD, DO) with current medical license in Maryland.
2. Employs competent personnel with credentials that meet CLIA'88 standards to perform testing.
3. Provides consultation as to the appropriateness of the testing ordered and interpretation of test results.

Laboratory Director

1. Doctorate degree (MD, DO, DPM, PhD) with 20 CMEs required in approved program in laboratory practice - or - 1 year of directing/supervising non-waived tests. Or, Master's degree in biological or chemical science with 2 years of laboratory training or experience at the complexity level of the certificate. Or, Bachelor's degree in biological or chemical science with 4 years of laboratory training or experience at the complexity level of the certificate.
2. Provides overall operation and administration of the laboratory including the following;
    a. Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services in all aspects of test performance, which include pre-analytic and post-analytic phases of testing.
    b. Ensure that the physical facility and environmental conditions of the laboratory are appropriate for the testing performed and provide a safe environment in which testing personnel are protected from chemical and biological hazards.
    c. Ensure that the test methodologies selected are capable of providing the quality of results required for patient care.
    d. Ensure that the regional laboratory is enrolled in a HCFA approved proficiency testing program when and where it is appropriate.
    e. Ensure that quality control and quality assurance programs are established and maintained to assure the quality of the laboratory services provided and to identify failures as they occur.
    f. Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system.
    g. Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance specifications are identified and that patient test results are reported only when the system is functioning properly.
    h. Ensure that reports of test results include pertinent information required for interpretation.
    i. Provide consultation to the laboratory's clients on matters relating to quality of the test results reported and their interpretation concerning specific patient conditions.
    j. Visit each jurisdiction annually.
    k. Conduct biannual site coordinator meetings and or participate in regional meetings where site coordinators can discuss regional laboratory issues.
    l. Attend Regional Laboratory meetings quarterly.
    m. Provide on-site, telephone or electronic consultation as needed.
3. The Laboratory Director for *Your Local Health Department* is *enter name of Laboratory Director* who can be reached at *enter phone number*.

Technical Consultant (or Supervisor); While most of the following duties will be the responsibility of the Laboratory Director in the Regional Laboratory System, some of these duties will be delegated to the Site Coordinator.

1. Same personnel requirements as Laboratory Director.

2. Responsible for the technical and scientific oversight of the laboratory including the following which may be delegated by the Laboratory Director;
    a. Select test methodology appropriate for clinical use of the test results.
    b. Verify test procedures performed and establish the laboratory's test performance characteristics including the precision and accuracy of each test and test system.
    c. Enroll and participate in a HCFA approved proficiency testing program.
    d. Establish a quality control program appropriate for the tests performed.
    e. Resolve technical problems and ensure that remedial actions are taken whenever test systems deviate from the laboratory's established specifications.
    f. Ensure that patient results are not reported until corrective action has been taken and the test system is functioning properly.
    g. Evaluate the competency of all Testing Personnel and assure that staff members maintain their competency to perform test procedures and test results promptly and accurately.
    h. Evaluate and document the performance of individuals responsible for testing at least semiannually during the first year the individual tests patient specimens. Thereafter, evaluations must be performed at least annually.
3. The Technical Consultant for *Your Local Health Department* is *enter name of Technical Consultant* who can be reached at *enter phone number*.

General Supervisor: High complexity Laboratories must have one General Supervisor who, under the direction of the Laboratory Director and supervision of the Technical Supervisor, provides day-to-day supervision of testing personnel and reporting of test results. If the General Supervisor does not have the qualifications for Laboratory Director or Technical Supervisor, they must have at least one year of laboratory training and experience in high complexity testing.

Clinical Consultant, (commonly performed by the Medical Officer): A Clinical Consultant is required for both moderate and complexity laboratories. The Clinical Consultant must;
1. Be a Physician (MD, DO, DPM) with current medical license in Maryland.
2. Provide consultation as to the appropriateness of the testing ordered and interpretation of test results.
3. The Clinical Consultant for *Your Local Health Department* is *enter name of Clinical Consultant* who can be reached at *enter phone number*.

Testing Personnel: At least a high school diploma or certificate of equivalency for waived or moderately complex testing. Bachelor's degree for high complexity testing.
1. Testing personnel are responsible for specimen processing, test performance, result reporting according to laboratory guidelines and procedures.
2. Each person may perform only those tests for which they have demonstrated competency.
3. Each individual performing testing must;
    a. Follow the laboratory's procedures for specimen handling, clinical tests, result reporting and maintain a log of patient test results.

b. Perform testing procedures according to written guidelines in the laboratory manual.
c. Perform QA and QC procedures according to guidelines in the laboratory manual and written procedures at specified intervals, including completion of all documentation.
d. Maintain records that demonstrate that proficiency testing samples are tested in the same manner as patient samples. Proficiency records must be logged into the patient testing log with the day's run and tested by the same person following routine QA and QC procedures.
e. Follow the established corrective action guidelines and procedures whenever test systems are not within the laboratory's (or manufacturer's) acceptable limits of performance.
f. Be capable of identifying problems that may adversely affect test performance or reporting of test results and either correct the problems immediately or notify the Site Coordinator, Technical Consultant, or Laboratory Director.
g. A list of personnel qualified to perform waived tests are on the HCFA-209 attached to the Appendix of this document.

Site Coordinator : This term does not appear in the CLIA rules, but has been developed to meet the operational needs of sites in Maryland. This individual is the key to successful participation in the Regional Laboratory System. The major responsibility of this position is to ensure functional communication between the Laboratory Director, Technical Supervisor and Testing Personnel. This person supervises Testing Personnel ensuring adherence to laboratory procedures and QC/QA guidelines. It is suggested that someone with clinical experience and a Bachelor's degree or an RN fill this position as it will require understanding of the technical aspects and clinical relevance of laboratory testing.

1. The Site Coordinator for *Your Local Health Department* is *enter name of Site Coordinator* who can be reached at *enter phone number*.
2. Each local health facility will assign at least one person to act as the Site Coordinator. This position will be responsible for the personnel and quality of clinical laboratory testing at their respective county, district or site and work directly with the Technical Supervisor or Laboratory Director to ensure compliance of CLIA testing regulations.
3. Record Keeping and Meetings
   a. Maintain all testing procedures performed at the site in a Procedure Manual that is kept updated and reviewed annually by the Laboratory Director. The Laboratory Manual must be readily available to all testing personnel.
   b. Maintain records of testing personnel to include education, licensure or certifications, technical training, in-service training, competency testing and testing experience. Alternatively, the local health department's personnel section may serve this function.
   c. Maintain records for at least one year of all patient logs, QC reports, proficiency tests, and retired procedures.
   d. Report volume of tests performed at all sites at intervals specified by the Technical Consultant or Laboratory Director.

e. Meets with Technical Consultant or Laboratory Director at least twice a year for quality assurance updates, education, update and review of CLIA regulations with the Technical Consultant or Laboratory Director.
f. Maintain a copy of the Regional CLIA certificate, the Regional Quality Assurance Manual, and copies of reference laboratory's CLIA certificates.
g. Maintain records of quality assurance activities, staff meetings in which quality assurance is discussed, problems and resolutions or corrective actions for quality control, proficiency testing, employee competency testing, staff training and result reporting. Some of these functions may be performed by the personnel section of the local health department.

4. Quality Control
   a. Ensure quality control is performed on all testing methods as specified in the Laboratory Procedure Manual.
   b. Ensure that corrective action is taken whenever quality control limits are exceeded.
   c. Send quality control reports to the Technical Consultant or Laboratory Director at specified intervals for review and signature
   d. Competency Evaluation
      i. Ensure that competency evaluation of testing personnel is completed prior to performance of test procedures on client specimens.
      ii. Maintain competency evaluation records, or ensure that the local health department personnel section maintains them.
5. Proficiency Testing
   a. Coordinate internal and/or external proficiency test performance. Report the results to the Technical Consultant or Laboratory Director within the time frame indicated by the proficiency test.
   b. Follow up on all unacceptable performance with corrective action documentation. This must be done in consultation with the Technical Consultant or Laboratory Director
6. Safety and Working Environment
   a. Maintain a safe working environment for all personnel and clients by developing plans to address all OSHA / MOSHA safety rules
   b. Ensure that all equipment, machines or instruments are maintained and are safe to operate. Keep records of applicable service and maintenance agreements and temperature records as applicable.
   c. Retain records for at least two years.
7. Training and Development
   a. The local health agency will provide an orientation program for all new employees who will perform clinical testing that include:
      1) Blood Borne Pathogen Rule
      2) Material Safety Data Sheets (MSDS) and Right to Know
      3) Infection Control Plan
8. Personnel Listing:
   a. Completed Organizational Structure document, which lists;

1) Names of administrative personnel (Medical Director/Health Officer, Clinical Administrator and Laboratory Director and Technical Consultant)
2) Address of each facility where tests are performed
3) Names of each section (program) supervisor and their phone numbers.
4) Tests performed and the manufacturer of each
5) This document must be kept up to date to reflect all personnel changes

A copy of the Organizational Structure for *Your Local Health Department* is included in the appendix. A blank copy on diskette or CD-ROM may be available to facilitate editing and updating – see the Laboratory Director.

IV. Proficiency Testing, Competency Evaluation and Training

Internal Proficiency Testing The CLIA'88 legislation requires that each laboratory, regardless of complexity level, must demonstrate that tests performed in different sites yield equivalent results for the same analyte. The Regional Laboratory Systems maintains its own internal proficiency testing system, using challenge material provided by an external vendor or by DHMH and evaluates the results.

1. Each test in the waived category will be tested with two challenge sets (based on sample availability).
2. The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods.
3. The appropriate mix of analytes and number of challenges is at the discretion of the Laboratory Director.
4. Records of internal proficiency testing must be maintained on site or in the health district's central office for two years.

Corrective Action: In the event that a site receives less than 100% on any proficiency challenge, the Laboratory Director must approve, review and sign the corrective action. The corrective action must be filed for two years.

Review of Proficiency Testing: All testing personnel will review and initial final proficiency testing reports which discuss results. The objective is to instruct testing personnel in regard to procedures and potential sources of error, testing problems or variation in testing results.

Competency Evaluation of Personnel: The CLIA'88 legislation requires a mechanism to evaluate competency in test performance for each person who performs a clinical diagnostic test.

1. Initially, each person who will be performing this test will successfully analyze 2 samples during a training session. Results of the rapid test and standard EIA/WB will be compared and each tester must achieve 95% accuracy in their performance, or undergo further training. As new personnel are trained to perform this test, DHMH

may continue to provide this initial competency at the discretion of the director, based upon the overall performance of test personnel.
2. The Laboratory Director, Site Coordinator or other designated person must critically observe the individual being checked to determine that procedural methods and protocols are followed correctly, the technique is adequate and that safety guidelines are followed.
3. Materials used for testing may be drawn from a variety of sources which may include proficiency testing material or actual patient samples.
4. Each person performing testing must be checked initially prior to performing a test for clinical purposes, again after six months and yearly thereafter.
5. Records of competency evaluation must be maintained on site or in the health department central office for two years. The competency evaluation form for each individual will be kept with their personnel records. A summary form listing each employee and the tests for which they have been checked will be maintained by the site coordinator. (see examples in appendix)

Training: Ongoing training is an essential quality assurance event. Accrediting agencies require that training take place and that attendance is documented. It does not matter whether an individual receives their training on site or off site or whether it is a short 15 minute 'consulting' session or an all day program; it still must be documented. Documentation needs to be readily available to the Site Coordinator. A training schedule for each person performing testing will be maintained by the Site Coordinator. Those items which require annual training are listed in section 6 of the Site Coordinator responsibilities in the Personnel section.

Visits and Consultation: All visits and consultations by the Laboratory Director and Technical Consultant must be recorded in a log. This log may be filed along with the records for training. Prior to a visit from the Laboratory Director or Technical Consultant, the Site Coordinator should prepare a simple, written agenda of issues they, or the testing personnel, wish to discuss. The Laboratory Director will sign and date the agenda and the visit log. It would also be advantageous for the testing personnel who might have questions to be on hand during the visit so that the Laboratory Director or Technical Consultant can address any issues personnel wish to discuss.

V. Laboratory Facility

General Considerations: A separate area needs to be provided where equipment and supplies along with the testing equipment will be located. When testing is performed in-house, this area will serve as the testing area. Minimal requirements for laboratory space are as follows;
1. Facilities and grounds are to be maintained in a state of cleanliness, order and efficiency in a manner conductive to productivity.
2. Persons who work in the laboratory area will maintain an orderly work area.
3. The laboratory must be constructed, arranged and maintained to ensure space, ventilation and appropriate utilities necessary for conducting all phases of testing,

including pre- analytic, analytic and post-analytic as appropriate.

4. Ambient temperature and humidity must be controlled during all seasons to minimize effects on reagents and test systems. Air quality must be sufficient that test results are not compromised and personnel are not endangered.
5. Storage must be convent to the laboratory, sufficient for operational need and provide an environment which is appropriate for all stored materials. The storage space must be neat and free of unessential material and efficiently organized.
6. Facilities for hand washing must be available in or immediately adjacent to the laboratory area.

Safety: Safety precautions must be established, posted and observed to ensure protection from physical, chemical, biochemical, electrical and biohazardous hazards. Special considerations must be made to ensure that the area is safe for all people, especially children, who do not have a technical understanding of the potential hazards. Patients must never be left in the laboratory area alone

1. A **Safety Manual** or document shall be immediately available in the laboratory area for all testing personnel to consult. A specialized manual specifically directed toward safety in the laboratory may be contained within the Laboratory Procedure Manual.
2. A **Blood Borne Precaution Plan** or document shall be immediately available in the laboratory area for all testing personnel to consult. It may be included as part of the Safety Manual.
3. **MSDS** sheets

VI. Laboratory Equipment and Instrumentation

General Considerations:

1. Laboratory equipment, including refrigerators, instruments and test systems status are monitored under a preventative maintenance program.
2. Equipment will not be used unless it is in a safe and reliable operating state.
3. Electrical equipment will be installed, connected and grounded according to manufacturer's instructions.
4. Maintenance schedules will be established based on manufacturer's operating manuals.
5. Incubator, refrigerator and freezer temperatures will be monitored daily with a certified or calibrated thermometer and recorded on a temperature log. Calibrated (non-certified) thermometers will be checked against a certified thermometer (NBS traceable) annually to establish precision of non-certified thermometers in daily use. An outside calibration and maintenance organization can provide this function and furnish documentation which should be dated and signed by the person performing the calibration.
6. Equipment will be regularly cleaned by testing site personnel as per manufacturer's recommendations.
7. All records of preventative maintenance will be documented in the Equipment Maintenance Log Book or equivalent

8. All records of corrective action taken and repairs are documented in the individual units equipment maintenance log or suitable ledger maintained by testing site personnel.
9. Equipment monitoring records are regularly reviewed, dated and signed by the Laboratory Director.

VII. Laboratory Reagents

Reagents are defined as any chemical substance used to dissolve, digest, extract, react with or otherwise interact with any sample or analytical component of the sample. The following is not an exhaustive list but rather indicates some key issues

1. Reagents used in the Regional Laboratory system will be of the appropriate quality for the intended use.
2. All reagents shall be marked with date of preparation or receipt.
3. All reagents shall be marked with date opened.
4. Expired reagents may never be used for clinical testing.
5. All reagents shall be labeled with expiration date.
6. Reagent or lot validation, if required, will be identified in the test procedure.
7. All reagents shall be labeled to indicate content, and when appropriate titer, strength or concentration. All reagents shall be labeled with associated hazards: health, fire, reactivity and specific hazards according to MIOSHA requirements
8. All reagents shall be properly stored according to manufacturer's instructions.
9. Reagent shelf life shall be strictly observed.
10. Components of reagent kits of different lot number are not interchangeable unless specified by the manufacturer.
11. Material Safety Data Sheets (MSDS) for all reagents/chemicals are maintained at the immediate work site and easily accessible to testing personnel. Their location will be posted.

VIII. Test Procedures

All work will be accomplished according to a written procedure selected, developed and optimized for each situation in advance of the actual work. Procedures used will be equivalent to or exceed requirements recognized by existing state or federal regulations. For clinical testing at the Regional Laboratories, procedures will follow National Committee for Clinical Laboratory Standards, Approved Guideline, Volume 4, Number 2, Clinical Laboratory Procedure Manuals. These procedures will include the following criteria as applicable:

1. Qualifications for acceptance and rejection of samples.
2. Safety concerns unique to particular procedure.
3. Testing procedure (analytical methodology and principles) including limitations of procedures, reagents, and calculation explanation.
4. Quality control and calibration requirements.
5. Corrective action guidelines.
6. Report handling procedures and instructions on reporting results, reportable ranges, test values outside of reportable ranges and critical or panic values.

7. Disposal of specimens and related by-products is performed in accordance with y*our Local Health Department's* "Waste Handling and Disposal Policy".
8. Reference materials pertinent to specific procedures.
9. Appropriate criteria for specimen storage and preservation to ensure specimen integrity until testing is completed.
10. Criteria for the course of action to be taken in the event that a test system becomes inoperable.
11. Criteria for referral of specimens, including procedures for specimen submission and handling.
12. These procedures shall be approved, dated and signed for use at least annually by the Laboratory Director. Changes in the procedures must also be approved, signed and dated by the Laboratory Director or designated Technical Consultant.
13. Procedures must be re-approved, signed and dated if the directorship of the laboratory changes.
14. The laboratory must maintain a copy of each procedure with the dates of initial use and discontinuance for a period of two years.

IX. Sampling Procedure and Specimens

Analysis of specimens for diagnostic, therapeutic or clinical management requires that the specimen must be unequivocally identifiable, adequate and reflective of the clinical condition in question. If a specimen does not meet such criteria, it should not be tested as the data is misleading and may result in inappropriate treatment or management of the patient or client.

Minimal Criteria: Regardless of whether a specimen is tested at the site of collection or in a more distant location, the following conditions always apply,

1. Specimen must be appropriate for the intended analysis as specified in the Procedure Manual.
2. The specimen must be collected in a manner as specified by the Procedure Manual.
3. The specimen must be free of contaminants (e.g., dirt, soap, alcohol etc.).
4. The specimen must be tested as soon as possible after collection and within the time frame specified in the testing method (see Procedure Manual).
5. For specimens which are not tested directly, but must be transported to another site for testing, as for confirmation testing, the following conditions shall also apply;
    a. The specimen must be collected in an appropriate container as specified in the Procedure Manual. Usually, this means the container must be clean, dry, sterile, contain only those additives or preservatives appropriate for the procedure, and provide a leak proof seal (and tamper proof where appropriate). Specimens submitted in leaking containers may be contaminated (yielding false results) and pose a hazard to anyone who handles or works with the specimen; leaking specimens will be destroyed without testing.
    b. The specimen will be transported to the laboratory or testing area under environmental conditions appropriate to preserve and protect as specified in the Procedure Manual. (e.g., refrigerated urine, swabs at room temperature etc.)

Refrigerated or chilled specimens should be transported using a 'cold pack' or other ice substitute – the use of 'wet ice' is not acceptable.

c. A tracking system must be used to enable the submitting facility to identify where, when and to whom the specimen was sent, and whether the results have been returned and charted in a timely manner.
d. Every specimen will be submitted with a requisition appropriate for the test requested as specified in the Laboratory Procedure Manual.
e. The specimen must be unequivocally identified with patient specific information which matches that of the test requisition. Specimen labels must be attached to the container which directly contains the specimen, not on wrappers, boxes or bags which contain the specimen. Unlabeled specimens will be destroyed without testing. At a minimum, the requisition will contain;
    1. Patient name or other unique identifier.
    2. Specimen type and collection procedure where pertinent.
    3. time of specimen collection.
    4. Test(s) requested.
    5. Any other information required for test performance and result reporting as specified in the laboratory Procedure Manual.
f. The receiving laboratory retains the right to reject any specimen which is less than unequivocally identified and submitted with out all of the testing information needed. Thus, it is the submitter which bears the responsibility to assure that all requested information is legible, complete and accurate

X. Analytical Methodology

Standardization: All procedures and measurements are performed using standard methods employing the following parameters:

1. Procedures recognized as valid through peer review in literature.
2. Procedures developed and certified by manufacturers.
3. Procedures mandated by regulatory agencies or other legal requirements.
4. Procedures which are FDA approved

Applicability : The following applies for all tests subject to The Clinical Laboratory Improvement Act - 1988 regulations:
If the lab modifies manufacturers' procedures **in any way** or develops in-house tests, full pre-use validation is required. These pre-use validations include verification and establishment of the following applicable characteristics:

1. accuracy
2. precision
3. analytical sensitivity
4. analytical specificity
5. reportable range of patient results
6. reference range
7. calibration and control procedures.

Public Information: The laboratory will make the following information available to anyone upon request;

1. Testing methodology
2. Basis for reference ranges.
3. Test interferences or procedure limitations.
4. Sensitivity, Specificity and Predicative value

XI. Quality Control & Assessment

Regardless of complexity level, each laboratory performing tests must establish and maintain a system that ensures accurate reporting of results and optimal specimen integrity and identification throughout the testing process. Regional Laboratory System will utilize a standard approach based on good laboratory practice. The items below are taken from the CLIA requirements published in the Federal Register;

1. Each laboratory must have a written policy indicating the quality control procedures and criteria. These procedures commonly will be part of the individual test procedure.
2. Routine quality control must be at least as frequent as the manufacturer's specifications for including controls. (see QC interval table above)
3. Control material should monitor both normal and abnormal range and correlate with the specimen matrix. In practice, an HIV-1 positive control, an HIV-2 positive control, and a negative control will be used as routine control materials for each test qualitative test, such as OraQuick ADVANCE®, at intervals specific for each test.
4. All control results and remedial actions must be recorded and records kept for at least one year.

Data Review

1. All laboratory procedures are to be reviewed in a timely manner reflective of their importance to the laboratory operation and time frame in which they are productive.
2. If laboratory procedures are altered, they must be approved by the Laboratory Director (or designate) initialed and dated until such time that they are retyped.

Report Generation

1. All finished reports are reviewed prior to release for clarity and correctness by appropriate section personnel.
2. Keep original or exact duplicate report according retention schedule. Follow established procedures for reporting critical findings. The requester/user must be notified when changes occur that affect results or interpretation of those results.
3. Results listed in clinic logs must be traceable to the final report in the client's chart.

Communication Logs: Each laboratory will maintain a record of communications that are a result of breakdowns between the laboratory and individuals authorized to receive test results that require corrective action be taken.

1. All complaints and problems reported to the laboratory as well as corrective action taken are to be documented and instituted when follow up activity is required.

2. All laboratory or reporting errors will be documented in this log along with the corrective action taken.
3. All requests for clarification of client information submitted with a specimen to a testing laboratory will also be filed in the communications log.

Quality Assessment: An ongoing assessment of quality indicators needs to take place which measures the efforts of continuous quality improvement. This kind of exercise is very site specific and deals with those issues that are of particular importance to *your Local Health Department.* As an example of a quality assessment exercise, consider the following:

1. Review client logs (or equivalent) for any given clinic over a period of 3 months.
2. Randomly select three clients from each month when testing was performed
3. Count the number of times the QC Logs indicate that the QC was performed for that clinic or week. i.e. were the appropriate QC checks done prior to testing clients and can the records be found.
4. Recover the client records and find the test results.
5. What percent of the time was the QC correctly performed. What percent of the time did the test result actually make it to the client record.
6. Do these statistics show improvement over the year? If not, what will you do about it. In the following year, did your efforts make any difference?

It is up to the Site Coordinator together with the Technical Consultant (or Lab Director) to develop a system of ongoing quality assurance monitors.

XII. Records

Records are the heart of any Quality Assurance program because they document every aspect of laboratory activities. The attitude taken by most accrediting and inspecting agencies is that "*If you did not document it, then you did not do it*".

1. Quality assurance records will be designated by laboratory management. It is the responsibility of the testing personnel to keep designated records current for all work or operations performed.
2. Designated records shall be understandable to other testing personnel and supervisors not directly connected with the specific test procedure, but are not necessarily to be written for the "untrained person" to interpret.
3. Unauthorized changes to, loss of, or destruction of designated records are not permitted.
4. Data will be recorded on work sheets using permanent ink. Pencils and correcting fluid are not permitted. If an error is made, simply draw a line through the erroneous data and write the correct data above or beside the mistake along with your initials.
5. Data in the form of charts, instrument recordings, and printouts will be given suitable identification and attached to or referenced in work sheets or notebooks.
6. Completed reports and records are filed by test type and month/year.
7. In view of the possible legal use of some of the data, all records shall be maintained in such a way as to maintain credibility at all times.

8. Reports and records pertaining to laboratory testing are to be maintained for a minimum of one year.
9. Specimen records must include:
    a. Accession number or other specimen identifier,
    b. Time and date of receipt by laboratory
    c. Reason and condition of unacceptable specimens where that condition exists
    d. Dates of each step of testing
    e. Final report with laboratory test parameters and identification and/or signature of testing personnel - where feasible,
    f. Name and address of the laboratory location at which the test was performed.

Errors: Should an error in reported patient results be detected, the individual responsible for initiating the test (e.g. physician or 'the submitter' shall be notified in a timely manner by a laboratory supervisor or site coordinator. Communication shall be by telephone and shall be documented in the comment section of the flow sheet, clinic log, or log book and on the original (incorrect) report. A corrected report shall be generated and be designated "Corrected Report" and then sent to the submitter. The original and corrected copies shall be stapled together and filed in the usual manner. The phrase "Corrected Report" shall be highlighted and placed on top.

Corrective Action Reports: In minor cases where something needs to be corrected, simply noting what was wrong and what was done on the appropriate QC Log sheet should be sufficient. However, when the event takes more than one or two lines to explain and indicate the action taken, a "Corrective Action Report" must be completed and filed. Corrective Action Reports lists:

1. Who is/was involved
2. What happened and how
3. When did it happen
4. Whether any clients were involved (ie erroneous results reported) and/or were there any injuries.
5. What corrective action was taken and how will that action prevent the problem from occurring again.
6. Review by Site Coordinator, Technical Consultant, Laboratory Director and testing personnel involved.

There are two primary Corrective Action Reports, one general form for testing problems, and one specifically for internal proficiency testing failures. Each is designed to document and assist in the evaluation of the type of problem that occurred. They will allow for review of the problems observed and provide a basis for developing a broader corrective measure.

XIII. Appendix

- Copy of Regional Lab CLIA certificate for this laboratory

- Organizational Structure
- HCFA-209 which lists persons who perform waived tests
- Copies of CLIA certificates for reference laboratories
- Quality Assessment Plan, including Maintenance Protocol
- Worksheets: (blank copies, current procedures only)
  - Individual Competency Record
  - Site Competency Summary
  - Quality Control Logs
  - Monthly Test Volume
  - Corrective Action forms
  - Communication forms
  - Attendance and Visit records